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NUCLEAR WASTE MANAGEMENT PROGRAM PROCEDURE

NP 16-1
CORRECTIVE ACTION
Revision 3

Effective Date: 06/03/03

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	(printed name)	(signature)	date

1.0 Purpose and Scope

This procedure prescribes the SNL WIPP process for identifying, documenting, evaluating, preventing, controlling, and correcting conditions adverse to quality, and for ensuring continuous improvement.

All SNL WIPP personnel are responsible for detecting and preventing conditions adverse to quality, and for promoting continuous improvement of processes and activities. Management is responsible for developing and fostering an environment in which continuous improvement is a fundamental and integral part of the SNL WIPP's mission and daily conduct. Management at all levels should foster a "no fault" attitude to encourage the identification of conditions adverse to quality.

Acronyms and definitions for terms used in this procedure may be found in the NWMP Glossary located at the Sandia National Laboratories (SNL) NWMP On-line Documents web site.

2.0 Implementation Actions

2.1 General

Conditions adverse to quality (CAQ) are categorized based on the effect the CAQ has on compliance to regulatory requirements for safety, operability, TRU waste containment and the effective implementation of the CBFO QAPD.

A CAQ is a deviation from a requirement, a deficiency, or some other condition that adversely impacts the quality of a process or product including failures, malfunctions and technical inadequacies.

A significant condition adverse to quality (SCAQ) is a condition that, if uncorrected, could have a serious impact on safety, operability, waste isolation, regulatory compliance demonstration or effective implementation of the SNL WIPP quality assurance program.

Any changes to CARs and/or Corrective Action Plans (e.g., date extension requests) shall receive the same level of approval as the original CAR and/or CAP.

2.2 Processing Conditions Adverse to Quality and Significant Conditions Adverse to Quality

CAQ and SCAQ are documented, reported to the appropriate level of management responsible for the condition and tracked through the Corrective Action Request (CAR) process. The SNL WIPP Quality Assurance Tracking System Coordinator (QATSC) is responsible for maintaining the SNL WIPP Corrective Action tracking system database for CARs. The QATSC will make final distribution of all completed and verified CARs. Distribution of the completed CAR will include appropriate management, responsible individuals, and the SNL WIPP Records Center. Phases of the CAR process are documented using the following forms:

CAR Phase	CAR Form Number
Initiation	NP 16-1-1 (Corrective Action Request)
Response	NP 16-1-2 (Corrective Action Plan)
Verification	NP 16-1-3 (Corrective Action Verification)

2.2.1 Initiation of a Corrective Action Request

All individuals working on SNL WIPP activities are responsible for identifying and reporting conditions which could adversely affect quality. Documentation of CAQ shall identify and describe the deviation in detail that does not conform to SNL WIPP Procedures (NP/SP), Test Plans, Analysis Plans, etc. Any individual working on SNL WIPP activities may initiate a CAR. The CAR process should be initiated as soon as practical once a deviation is identified.

The initiator of the CAR should consult a SNL WIPP QA staff member if the adverse condition appears serious enough to consider categorizing it as a SCAQ. Final determination that a condition will be categorized as a SCAQ shall be made by the QA Team Lead, or by the Audit Team Leader during a QA audit. Determination of whether or not the SCAQ warrants issuance of a Stop Work Order (SWO) shall be made in accordance with the process described in Section 2.3 below.

After obtaining a CAR number from the QATSC, the CAR initiator coordinates completion of blocks 1 through 7 of the Form NP 16-1-1 (Corrective Action Request, Appendix A) in accordance with the flow chart in Appendix E. After obtaining the SNL WIPP QA staff member's concurrence signature, the initiator shall forward a copy of Form NP 16-1-1 to the applicable SNL WIPP manager/delegate, and send the original to the QATSC to initiate the tracking process. Note: During an SNL WIPP QA audit or surveillance, the Audit Team Leader has the authority to initiate SCAQ CAR's (See NP 18-1, Audits and Surveillances).

2.2.2 Corrective Action Plan: Response and Response Evaluation to a Corrective Action Request

The SNL WIPP manager responsible for the work activity (or the manager's delegate identified in block 6 of the CAR form) shall prepare and submit a Form NP 16-1-2, Corrective Action Plan (CAP) to an SNL WIPP QA staff member. The CAP shall address the following items for each category:

CAQ	SCAQ (plus items identified in a CAQ)
Name of individual responsible for the action; Estimated completion date; Remedial Action; Investigative Action; Causal code; and Actions to preclude recurrence (optional).	Identification of the root cause of the condition, including documentation and results of the of the root cause determination; (see section 2.4 for additional items to address for recurring conditions); and Actions to Preclude Recurrence.

in block 2 of the CAP, and should be submitted to an SNL WIPP QA staff member normally within 30 calendar days, or within 10 calendar days for a CAR documenting a SCAQ.

A SNL WIPP QA staff member shall review and evaluate the proposed corrective actions described on the CAP, and if acceptable, indicate concurrence in block 4, and returns the approved CAP to its author. The author and SNL WIPP manager then sign concurrence of the proposed corrective action(s) in block 3 and retain a copy of the approved CAP for their records. The original CAP Form is then forwarded to the QATSC to enter into the Corrective Action Tracking System.

If the proposed corrective actions listed on the CAP are not acceptable to the SNL WIPP QA staff member, the QATSC will be notified when a revised response has been received, and the SNL WIPP Corrective Actions Tracking System will be updated. The SNL WIPP QA staff member shall confer with the responsible SNL WIPP manager or delegate(s) to reach consensus on acceptable corrective actions.

The CAP author has overall responsibility for coordinating all activities to ensure timely completion of all corrective actions listed on the CAP. For CARs with multiple deficiencies, this may require coordination with several individuals from different organizations.

If additional information in the response reveals that a Stop Work Order (SWO) is necessary, the stop work process described in Section 2.3 shall be implemented.

2.2.3 Follow-up Verification and Closure of a Corrective Action Request

When all approved corrective actions have been completed, the CAP author shall notify the QATSC. The QATSC shall notify a SNL WIPP QA staff member that corrective action verification is needed.

The SNL WIPP QA staff member selected shall evaluate and verify completion and effective implementation of all corrective actions for the CAR, document this verification on Form NP 16-1-3, and notify the QATSC that verification is completed. If results of the verification are unsatisfactory, the CAP will be revised appropriately, the QATSC will be notified of the results, and corrective action revised and re-verification performed. The SNL WIPP QA staff member will forward the original Form NP 16-1-3, and all supporting documentation to the QATSC. The QATSC will assemble all forms and supporting documentation to make a comprehensive QA record of the closed CAR for distribution to the responsible manager/individual(s) and the SNL WIPP Records Center.

2.3 Stop Work

Any person may identify a situation or condition (typically a SCAQ) for which a SWO is necessary. The potential stop work situation or condition shall be brought to the immediate attention and evaluated by the SNL QA Team Lead, the individual responsible for the activity, and the Carlsbad Programs Group (CPG) manager. When Environment Safety and Health (ES&H) is an issue (contact the SNL WIPP ES&H Coordinator), all personnel have the authority to stop work. If the work involves

a contractor, work stoppage shall be communicated to the contractor through the appropriate Sandia Contracting Representative.

If time is critical (to prevent personnel injury or prevent risk of noncompliance in Compliance Re-certification and Performance Assessment activities), the individual responsible for the activity may verbally direct that work be stopped. This shall be followed-up as soon as possible by initiating the CAR process, letter or memo documenting the Stop Work directive. The recipient of the SWO shall take immediate action to terminate the subject activity and develop corrective actions to correct the deficiency or condition that caused the work stoppage. Investigation, evaluation, remediation, verification, and documentation of the deficiency or condition shall be done in a CAR, letter or memo detailing all the actions required and performed to complete corrective actions to rescind the SWO. Other CAQ or SCAQ issues not specifically associated with the Stop Work condition(s) will be tracked, evaluated, documented and resolved separately from the SWO.

The SNL QA Team Lead and the SNL WIPP manager responsible for the activity have the ultimate approval to stop work (in part or total). The CPG manager and SNL QA Team Lead have the authority to rescind the SWO. The lifting of a SWO shall be documented by use of the Corrective Action Verification Form, letter or memo. Documentation shall state that work activities can be continued without risk of personnel injury or risk of jeopardizing mission critical quality affecting activities. The SNL QA Team Lead shall concur that proper QA controls are in place before the Carlsbad Program Group manager releases the Stop Work.

The SNL QA Team Lead and responsible individual(s) shall be notified and provided the results of the Stop Work evaluation through formal communications and distribution of Stop Work documentation generated during initiation, investigation, remediation, verification and resolution of the SWO.

2.4 Recurring Conditions Adverse to Quality

For recurring conditions (e.g., same process, activity occurring three times or more) adverse to quality, the SNL QA Team Lead, SNL WIPP Manager, Principal Investigator, or contractor for the activity shall initiate the CAR Process as described in Section 2.2. The following additional items shall be addressed in Block 2 of the CAP:

- Determination of the events that led to the deviation(s);
- Development of an understanding to the technical and work activities associated with the recurring condition;
- Determine the extent to which similar quality problems, or precursors to the deviation, have been recognized, and the impact of completed work;
- Consider suspending work (if SCAQ) associated with the applicable activity;
- Identify any generic implications and impacts on completed work;
- Suggest actions that can be taken by the responsible organization to preclude recurrence; and
- Determine the effectiveness of any corrective actions taken.

2.5 Trend Analysis

The trend analysis process provides a method to collect information from program participants (e.g., SNL WIPP program, customer, contractor) to analyze reported deficiencies, identify recurring conditions and root causes that are adverse to quality.

This analysis uses quality performance data identified, collected and routinely analyzed to assist in the improvement of activities and processes subject to the QA Program. The analysis shall take into account CARs issued both internally to the SNL WIPP program and from external program participants. CARs and conditions Corrected During the Audit/Surveillance (CDA/CDS) will be

evaluated to identify adverse trends, root cause and shall not be limited to one type of work or organization. The trend analysis should focus in areas reported by the causal codes (Appendix D), procedure deviations, timely completion of corrective actions, and other quality affecting activities identified during the trend period. The trend analyses are conducted semi-annually to provide prompt identification of trends adverse to quality.

The Assessment Task Lead or delegate shall gather information and prepare a Trend Analysis Report. Information in the Trend Analysis Report shall be reported to responsible SNL WIPP management, SNL WIPP QA organization, and customer for corrective action as applicable. The Trend Analysis shall be submitted to the SNL WIPP Records Center as a QA record.

3.0 Records

The following QA records, generated as a result of this procedure, shall be prepared and submitted to the SNL WIPP Records Center in accordance with NP 17-1 (Records):

QA Record	Preparer	Records Submitter
Form NP 16-1-1	Initiator	QATSC
Form NP 16-1-2	CAP Author	QATSC
Form NP 16-1-3	QA Staff Member	QATSC
Extension Request, as applicable	Responsible Individual(s)	QATSC
Supporting documentation	Responsible Individual(s)	QATSC
Recurring Condition Evaluation	CAP Author	QATSC
Trend Analysis Report	Assessment Task Lead	Assessment Task Lead or Delegate

4.0 Appendices

Appendix A: Corrective Action Request, Form NP 16-1-1
Appendix B: Corrective Action Plan, Form NP 16-1-2
Appendix C: Corrective Action Verification, Form NP 16-1-3
Appendix D: Causal Codes
Appendix E: Corrective Action Request Process Flow Chart
Appendix F: Corrective Action Plan Process Flow Chart
Appendix G Corrective Action Verification Process Flow Chart

Appendix A

NUCLEAR WASTE MANAGEMENT PROGRAM Sandia National Laboratories	**Corrective Action Request (CAR)**	**Form Number: NP 16-1-1** **Page ___ of ___**

1. Corrective Action Request Number: _____

Initiator: _____ Date: _____
Printed Name

2. Significant Condition Adverse to Quality (SCAQ)? ☐ Yes ☐ No Stop Work? ☐ Yes ☐ No

_____ Date: _____
SNL QA Team Lead or Audit Team Leader's Printed Name and Signature (ONLY required if SCAQ or Stop Work)

_____ Date: _____
SNL WIPP Responsible Manager's Printed Name and Signature (ONLY required if Stop Work)

3. Deviation identified during Audit/Surveillance No: _____ Other: _____

Supplier (if applicable): _____ Contract No: _____
LEAVE THIS BLOCK BLANK IF NOT APPLICABLE

4. Procedure Reference: _____ (Cite procedure & section, document, form, etc. with a brief description)

5. Deviation: (Provide sufficient detail to allow determination of appropriate corrective actions. Include attachments as necessary)

6. Proposed Corrective Action: Complete Form NP 16-1-2, Corrective Action Plan (CAP, Appendix B)

CAP Response Due Date: _____ (Normally 30 calendar days for CAQ or 10 calendar days for SCAQ)

Individual(s) Responsible for Submitting CAP (Point of contact for tracking system):

_____ Date: _____
Printed Name of SNL WIPP Manager Signature

_____ Date: _____
Printed Name of Delegate Signature

7. QA Staff Member Concurrence: _____
Printed Name Signature Date

Forward Copy to Manager/Responsible Individual(s) & Send Original To QATSC

Records Code: _____

Appendix B

NUCLEAR WASTE MANAGEMENT PROGRAM Sandia National Laboratories	**Corrective Action Plan (CAP)**	**Form Number: NP 16-1-2** **Page ___ of ___**

1. CAR No: _____

CAP Author: _____
Printed Name Signature

2. CAP Proposed Corrective Actions: (Include attachments as needed)

Notes: Each **CAQ** proposed corrective action must include the following:

- Name of individual responsible for the action;
- Estimated completion date;
- Remedial actions;
- Investigative actions (extent of deviation and impact on quality);
- Causal Code(s); and
- Actions to Preclude Recurrence (optional).

SCAQ's additionally require the following:

- Identification of the root cause of the condition, including documentation and results of the root cause determination (see section 2.4 for additional items to address for recurring conditions); and
- Actions to Preclude Recurrence.

3. SNL WIPP Manager/Delegate Responsible for Corrective Actions:

Name: _____ Date: _____
Print Signature

Name: _____ Date: _____
Print Signature

4. QA Approval of Proposed Corrective Actions: _____
Print Signature Date

Forward Copy to Manager/Responsible Individual(s) & Send Original To QATSC

Appendix C

NUCLEAR WASTE MANAGEMENT PROGRAM Sandia National Laboratories	**Corrective Action Verification**	**Form Number: NP 16-1-3** **Page ___ of ___**

1. CAR No: _____ Date all actions completed: _____

2. Actions taken to verify completion: (Including all documentation to be verified)

Notes:

Summarize actions taken for each deficiency.
Attach or reference objective evidence examined.
State if corrective action implementation was verified as complete for each deficiency.
Identify pending actions to resolve stop work in total.

3. Stop Work CARs only: ☐ Stop Work Rescinded in Total ☐ Stop Work Rescinded in Part

Name: _____ Date: _____
SNL QA Team Lead (print) Signature

Name: _____ Date: _____
SNL WIPP Responsible Manager (print) Signature

4. QA Verification of (Check One)

☐ Some ☐ All Corrective Actions: _____
Print Signature Date

5. QATSC Distribution: Section 5 to be filled in at time of distribution by the QATSC.

Name: _____ Date: _____
Print Signature

☐ Manager ☐ Responsible Individual(s) ☐ QATSC ☐ Records Center

Appendix D
Causal Codes

1. Equipment/Material Problem
   a. defective or failed part
   b. defective or inadequate material
   c. defective weld, braze, or soldered joint
   d. error by manufacturer in shipping or marking
   e. electrical or instrument noise
   f. contamination
   g. calibration

2. Procedure Problem
   a. defective or inadequate procedure
   b. lack of procedure
   c. failure to use procedure

3. Personnel
   a. inadequate work environment
   b. inattention to detail
   c. violation of requirement or procedure
   d. verbal communication problem
   e. other human error

4. Design Problem
   a. inadequate man-machine interface
   b. inadequate or defective design
   c. error in equipment or material selection
   d. drawing specification, or data errors

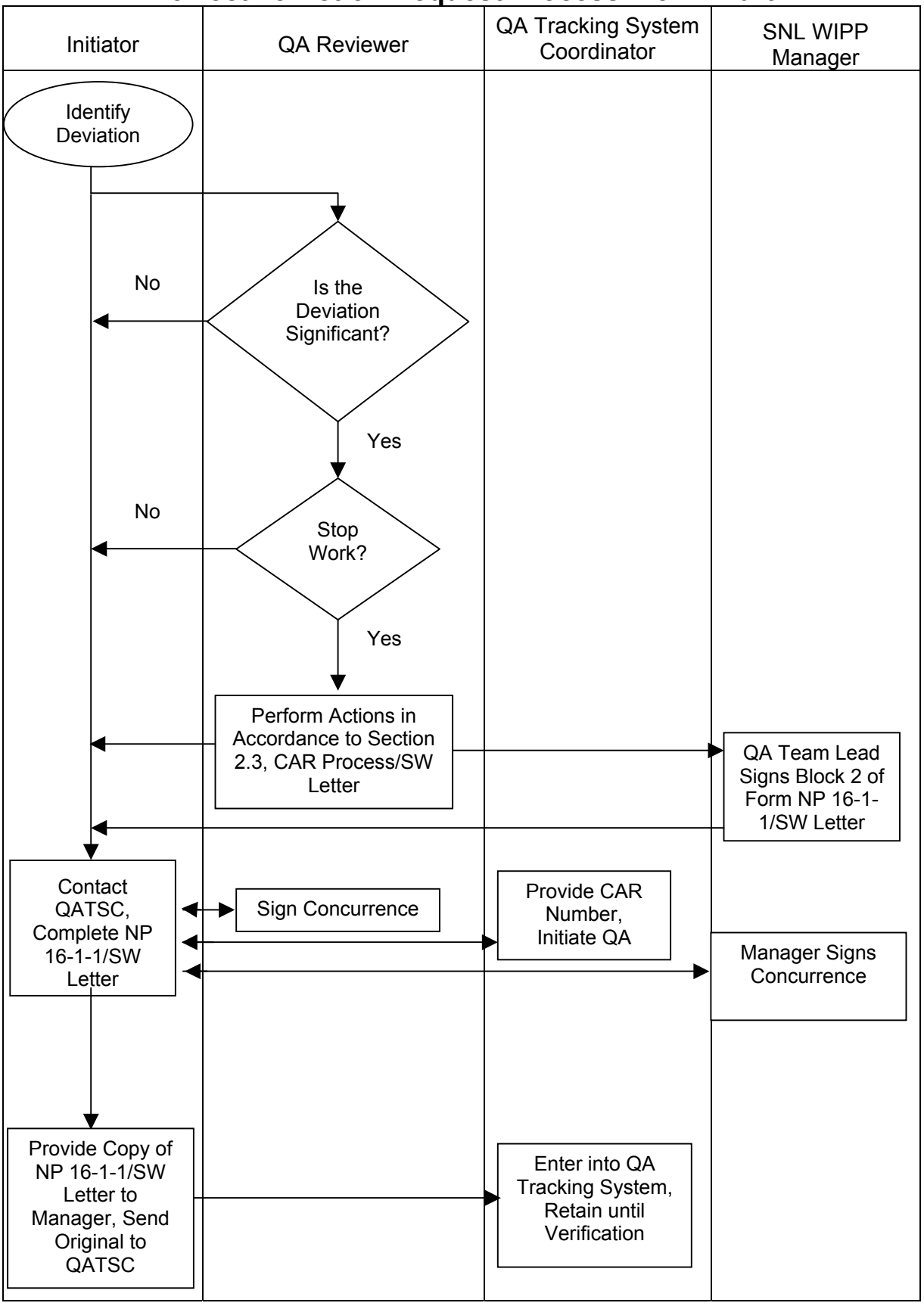
5. Training Deficiency
   a. no training provided
   b. insufficient practice or hands-on experience
   c. inadequate content
   d. insufficient refresher training
   e. inadequate presentation or materials

6. Administrative Control
   a. inadequate administrative control
   b. work organization/planning deficiency
   c. inadequate supervision
   d. improper resource allocation
   e. policy not adequately defined/disseminated/enforced
   f. other management problem

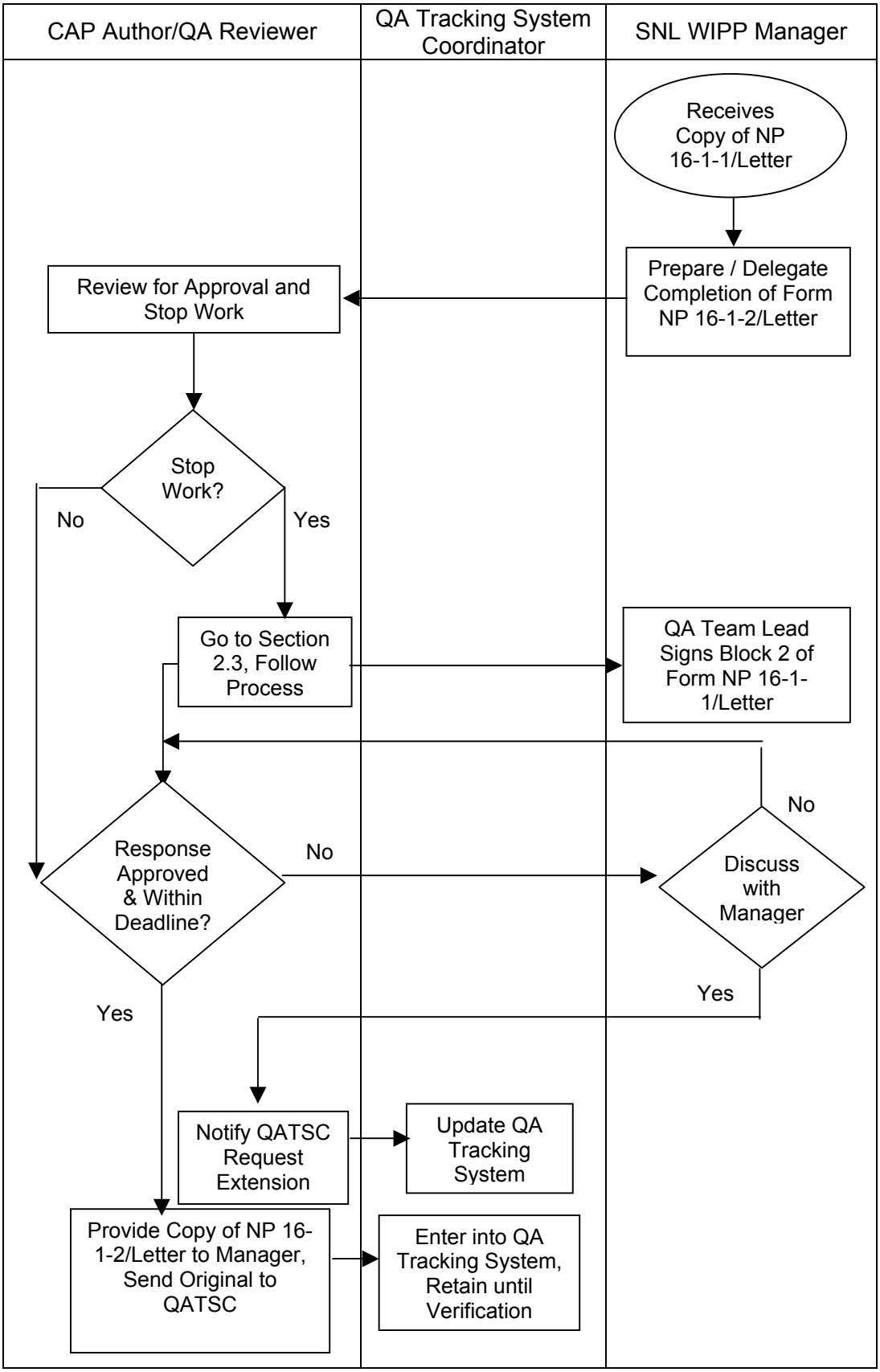
7. External Phenomena
   a. weather or ambient condition
   b. power failure or transient
   c. external fire or explosion
   d. theft, tampering, sabotage, vandalism

8. Other

Appendix E
Corrective Action Request Process Flow Chart



Appendix F
Corrective Action Plan Process Flow Chart



Appendix G
Corrective Action Verification Process Flow Chart